

**Notice of Allowability**

Application No.

09/500,747

Examiner

Kathleen M Kerr

Applicant(s)

GOKHALE ET AL.

Art Unit

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/22/03.
2. ☒ The allowed claim(s) is/are 23,25,28-39 and 45-58.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

## DETAILED ACTION

### *Application Status*

1. In response to the previous Office action, a non-Final rejection (mailed on August 1, 2003), Applicants filed a response and amendment received on December 22, 2003. Said amendment amended Claim 23, cancelled Claim 26, and added new Claims 45-58. Thus, Claims 23, 25, 28-39 and 45-58 are pending in the instant Office action and will be examined herein.

### *Priority*

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/119,363 filed on February 9, 1999.

### *Withdrawn – Objections to the Specification*

3. Previous objection to the specification for not having updated patent application information is withdrawn by virtue of Applicants' amendment.
4. Previous objection to the specification for being confusing as to its conflicting definition of module is withdrawn by virtue of Applicants' explanation in their arguments as well as the definitions clearly set forth in the claims as amended.

### *Withdrawn - Claim Rejections - 35 U.S.C. § 112*

5. Previous rejection of Claims 23, 25, 26, and 28-39 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term **inter-molecule linkers (ERL)** is withdrawn by virtue

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of Applicants' amendment and the Examiner's amendment below, the combination of which clearly set forth the definition of an ERL to one of skill in the art.

6. Previous rejection of Claims 23, 25, 26, and 28-39 under 35 U.S.C. 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendment wherein the structural feature of the RALs and ERLs are described by virtue of their location within a functioning PKS.

7. Previous rejection of Claims 23, 25, 26, and 28-39 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's amendment requiring the definite functionality of the claimed hybrid PKS.

#### **EXAMINER'S AMENDMENT**

8. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kate Murashige on February 2, 2004.

*Amendments to the Claims*

9. The claims been amended as follows:

---23. A hybrid modular polyketide synthase (PKS) comprising at least a first extender module and a second extender module of a different PKS from said first module,

wherein said extender modules are defined as consisting of the amino acid sequence from the N-terminus of the ketosynthase (KS) domain through the C-terminus of the acyl transferase protein (ACP) domain:

wherein the C-terminus of said first module is covalently linked to the N-terminus of a intra-molecular linker (RAL) and the N-terminus of the second module is covalently linked to the C-terminus of said RAL, and

wherein said RAL is defined as the amino acid sequence between the C-terminus of an upstream ACP domain and the N-terminus of an adjacent downstream KS domain; said ACP and KS domains occupying adjacent modules in the same reading frame;

wherein either said first module or second module is not covalently linked to said RAL in a naturally occurring polyketide synthase;

whereby the RAL effects the transfer of a nascent polyketide chain from said first module to said second module.---

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---45. A hybrid modular polyketide synthase (PKS) comprising at least a first extender module and a second extender module of a different PKS from said first module,

wherein said extender modules are defined as consisting of the amino acid sequence from the N-terminus of the ketosynthase (KS) domain through the C-terminus of the acyl transferase protein (ACP) domain:

wherein the C-terminus of said first module is covalently linked to the N-terminus of a inter-molecular linker (ERL) and the N-terminus of the second module is covalently linked to the C-terminus of said ERL, and

wherein said ERL is defined as a contiguous polypeptide comprising, in order, (1) the amino acid sequence beginning at the C-terminus of the ACP domain of the most downstream module of a first open reading frame and (2) the amino acid sequence upstream of the N-terminus of the most upstream KS domain of a second open reading frame, which second open reading frame is immediately adjacent to and downstream of said first open reading frame; and

wherein either said first module or second module is not covalently linked to said ERL in a naturally occurring polyketide synthase;

whereby the ERL effects the transfer of a nascent polyketide chain from said first module to said second module.---

#### ***Reasons for Allowance***

10. The following is an Examiner's statement of reasons for allowance:

The claimed subject matter has been clarified by the removal of the term "naturally occurring" in all occurrences, except one, in Claims 23 and 45. Particularly in the art of

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polyketide synthases wherein there is extensive genetic manipulation in the field, the term “naturally occurring” can be unclear. In this case, Claims 23 and 45 rely on the specification for the defined breadth of the term “first extender module” and “second extender module” and “different PKS” since the general description of the invention and the examples rely on using portions of known PKSs. While the claims no longer exclude the use of “modified” modules, they are clear based on the clarity of breadth of the term “PKS module” in the art.

The term “naturally occurring” has *not* been removed from the 5<sup>th</sup> paragraph of Claims 23 and 45, which contains a negative limitation; this limitation is crucial to define the claims around the art (see non-final rejection mailed 2/12/2002). Since the RALs and ERLs are structurally defined previously in the claims, this negative limitation only further defines the scope of the claimed invention. In considering the specification as a whole, as well as the art rejections (and removals thereof) of record, the metes and bounds of this negative limitation are clear.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

### ***Conclusion***

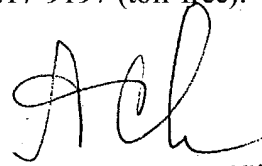
11. Claims 23, 25, 28-39 and 45-58 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



Kathleen M Kerr  
Examiner  
Art Unit 1652

February 2, 2004